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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,264	11/21/2003	Andre Jestin	042049-0105	8938
22428	7590	01/14/2005	EXAMINER	
FOLEY AND LARDNER			SALIMI, ALI REZA	
SUITE 500			ART UNIT	PAPER NUMBER
3000 K STREET NW				1648
WASHINGTON, DC 20007			DATE MAILED: 01/14/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/718,264	JESTIN ET AL.
	Examiner	Art Unit
	A R Salimi	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 November 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 2 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 November 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/514,245.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/14/04; 11/21/03; 11/23/04</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Election/Restriction

Applicant's election with traverse of Group I (claims 1-2) in Paper filed 11/23/2004 is acknowledged. The traversal is on the ground(s) that search and examination of other groups would not be unduly burdensome. This is not found persuasive because the separate classification of the subject matter is a *prima facie* showing of burden, which is not overcome by applicants' assertion to the contrary. Applicants further assert that the scope of examined subject matter should be expanded once the elected specie is deemed patentable. This is not persuasive, in the first fold the selection was not selection of species, since it was explicitly indicated that the sequences are considered independent and patentably distinct (see the previous action), which is not overcome by applicants' assertion to the contrary. The search for this case is considered to be highly burdensome, the adequate search has to be conducted in both in-house and commercial databases. Still further, the claims are not directed to only one sequence, the homologous sequences and fragments thereof also need to be searched. The information in databases almost double every few months, the office resources are now stretched to the limit, so only the selected sequence will be searched.

The requirement is still deemed proper and is therefore made FINAL.

Hence, claims 3-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected. Claims 1, 2 are considered only within the scope of elected sequence SEQ ID NO: 15.

The claims have been examined only to the extent of selected sequence designated as SEQ ID NO: 15. Applicants are requested to amend the claims accordingly by canceling the non-elected sequence(s).

Applicants are reminded to cancel the non-elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please update the information by inserting the U.S Patent number.

Claim Rejections - 35 USC § 112

Claims 1, 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite, the intended fragments or homologous is/are not defined. Is 10% identity or 10 nucleotides fragment intended? This affects the dependent claims.

Claims 1, and 2 are vague, indefinite and unclear for recitation of "homologous" or "at least 80% identity". The claims have been interpreted in view of the specification and it not clear what sequences are encompassed that are at least have 80% identity or homologous. Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Applicant has referred to various % identities, but there are no indications of the utilized algorithm to calculate the identity sequences. Furthermore, the calculation of "identity" is affected by variables such as the relative weight given to the sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. Since no art-recognized convention exists regarding the calculation of percent identity, the claims are vague and indefinite.

Still further, claims are confusing for recitation of "homologous" or homology that is likeness in structure between parts of different organisms due to evolutionary differentiation from the same or a corresponding part of a remote ancestor; there are no indication in the claims

regarding the intended evolutionary ancestor. Amending to “identity” would obviate this confusion.

Claim Rejections - 35 USC § 112

Claims 1, and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of antibody response utilizing SEQ ID NO: 15, does not reasonably provide enablement for inducing a protective response (vaccine). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims read on a vaccine development. Applicants are reminded that the field of vaccine development is considered to be highly unpredictable. According to the specification and the state of the art the currently claimed virus attacks the immune system and disables the immune response. A vaccine is considered to be protective wherein upon re- introduction of the disease would be able to induce a long lasting protective response against a challenge. The current specification does not teach nor enables a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof in to a host a protective response can be inferred. Absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims. The specification provides no teaching as to the induction of immunogenic protective response against the claimed antigenic fragments. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention.

Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequences identified as SEQ ID NO: 15. No other homologous sequences or fragments thereof were disclosed. There is no information in the specification that indicates Applicants were in **possession** of the claimed sequences. In addition, there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed homologous regions or where the region, fragments may encompass. Therefore, a written description of the all other claimed sequences of Circovirus type B should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a

particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception

does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,368,601 B1).

The teaching and claims of the above cited patent meets the broad recitation of the claims (see for example see claim 26). The sequences disclosed meet the “homologous”; “fragment thereof”; and “80% identity” limitations.

Art Unit: 1648

Claims 1, 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,660,272 B2).

The teaching and claims of the above cited patent meets the broad recitation of the claims (see for example claims 1 and 2). The cited patent broadly disclosed an isolated circovirus II and various circovirus type II isolates, which would inherently have the now claimed sequence. Moreover, the SEQ ID NO: 1 as disclosed in the above cited patent anticipates the broad limitations of claimed invention.

Claims 1, 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,391,314 B1).

The product taught and claimed in the above cited patent meets the broad recitation of the claims (see claims 1-5, and 9). The product taught by, 314 is directed to nucleic acid of circovirus II and fragment thereof, which clearly incorporates the limitations of now claimed invention.

Claims 1, 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,217,883 B1).

The product taught and claimed in the above cited patent meets the broad recitation of the claims (see claims 1-2, and 14, 22, 23). The product taught by Allan et al is directed to nucleic acid of circovirus II and fragment thereof, which clearly incorporates the limitations of now claimed invention. In addition, the ,883 disclosed the SEQ ID NO: 1 which anticipates the now claimed invention.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

1/11/2005

PRIMARY EXAMINER
A. R. SALIMI